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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,477	01/18/2002	Michael C. Stewart	26448-05730	5572

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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/054,477

Applicant(s)

STEWART ET AL.

Examiner

MATTHEW J. KASZTEJNA

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 84, 93, 95, 99, 103, 110, 112 and 122-125 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 84, 93, 95, 99, 103, 110, 112 and 122-125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on February 4, 2008, amended claims 84, 93, 95, 99, 103, 110 and 112; canceled claims 94, 96, 104, 111, 113 and 116-119; and new claims 122-125 are acknowledged. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 84, 93, 95, 99, 103, 110, 112, 122 and 124-125 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 5,725,479 to Knight et al.

In regards to claims 84 and 99, Knight et al. disclose a tissue dissector comprising: an elongated tube 12 having a central axis extending between a proximal end and a distal end and enclosing an endoscopic imaging element 5; and a dissecting, viewing and dilating unit 16 removably mounted on the distal end of the tubular body (see Fig. 16 and Col. 7, Lines 1-20), including; a transparent distal tip 16 having substantially conical tapered outer walls converging substantially symmetrically about the central axis to a blunt end for dissecting tissue, the tip being disposed on a distal end of the dilating unit to dissect tissue and facilitate passage of the tubular body through tissue under endoscopic visualization (see Figs. 1-2); and a non-inflatable

dilating element having a substantially olive-shaped or ovoidal exterior contour that is disposed symmetrically about the central axis and that gradually increase in size in the proximal direction from a distal edge thereof to a maximum cross-sectional dimension greater than the cross-sectional dimension of the distal end of the tubular body, the dilating element then decreasing in size to a proximal edge, for facilitating atraumatic expansion of tissue following dissection by the tapered distal tip (see Figs. 4-5 and Col. 4, Line 55 – Col. 5, Line 10).

In regards to claims 93 and 110, Knight et al. disclose a tissue dissector, wherein the maximum cross-sectional dimension of the dilating element is symmetrically disposed about the central axis and is at least two times larger than the cross-sectional dimension of the distal end of the tubular body (see Figs. 1-2).

In regards to claims 95 and 112, Knight et al. disclose a tissue dissector, wherein the dilating element is compressible in cross-sectional dimension as the working head 26 is made of a transparent material such as plastic. Plastic is fully capable of being compressed.

In regards to claim 103, Knight et al. disclose a tissue dissector having a removable dilating unit attached to the distal end of the flexible tube including a length of screw threads positioned on an outer surface of the tubular body near the distal end thereof, and wherein the dilating unit further comprises a threaded bore hole for engaging the length of screw threads and mounting the dilating unit on the distal end of the tubular body (see Fig. 16 and Col. 7, Lines 1-20).

In regards to claims 122 and 124, Knight et al. disclose a tissue dissector, in which a distal end of the endoscopic imaging element 5 is disposed near the transparent distal tip to provide endoscopic visualization therethrough (see Figs. 8-10 and Col. 4, Lines 55-67).

In regards to claim 125, Knight et al. disclose a tissue dissector, in which a spacer length is disposed intermediate the tip and the dilating element, the spacer length having an outer dimension less than the outer dimension of the dilating element and positioning the dilating element within an angle of the tapered outer walls of the tip to permit contact of the outer walls of the tip with a target vessel (see Fig. 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 123 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,725,479 to Knight et al. in view of U.S. Patent No. 5,688,286 to Yoon.

In regards to claim 123, Knight et al. disclose a tissue dissector having a removable dilating unit attached to the distal end of the flexible tube but are silent with respect wherein the tip is resiliently compressible. Yoon teaches of an analogous medical apparatus wherein distal end 64 as illustrated in Figs. 7-20 is formed of a resilient, flexible, compressible and expandable material that can fold or wrinkle, the

material defining a curved wall (see Col. 12, Lines 8-32). It would have been obvious to one skilled in the art at the time the invention was made to construct the dilating element in the apparatus of Knight et al. from a resilient material so the material itself can provide a bias for returning the safety shield to the extended position upon removal of force from tissue contact as taught by Yoon.

Response to Arguments

Applicant's arguments filed February 4, 2008, have been fully considered but they are not persuasive.

Applicant states that Knight et al. fail to disclose axial symmetry. Examiner disagrees. As seen in Figure 4, when viewed from a bird's eye point-of-view, the outer walls of the distal tip 16 converge substantially symmetrically about a central axis of the elongate tubular body. Furthermore, as also seen in Figures 4-5, the dilating element is also disposed symmetrically about the central axis of the elongate tube. The distal tip 16 is mounted in a symmetrical fashion to shaft 12, thus the dilating element and converging walls are symmetrical about a central axis as viewed from a top-down perspective. As broadly as claimed, Knight et al. meet the limitations of the recited claims.

Applicant further states that Knight et al fail to disclose a dilating element that is compressible in cross-sectional dimension. Examiner disagrees. The word compressible is interpreted as meaning the dilating element is merely *capable* of being compressed. Any material is *capable* of being compressed, and thus the plastic distal

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tip 26 of Knight is fully capable of being compressed. As broadly as claimed, Knight et al. meet the limitation of the recited claims.

In response to applicant's argument that Yoon is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Yoon teaches of safety shields placed on the distal end of surgical instruments used for accessing cavities within the body. Similarly, Knight teaches of a working element placed on the distal end of a surgical instrument used for accessing cavities within the body.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./
Examiner, Art Unit 3739

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